



NEW YORK LAW AND PROPOSED REGULATIONS ON ACCOUNTABLE CARE ORGANIZATIONS

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ISSUE

This report summarizes New York's law and proposed regulations on certifying Accountable Care Organizations (ACOs), specifically regarding antitrust immunity and other safe harbors for participating ACOs.

SUMMARY

ACOs are voluntary networks of physicians, hospitals, and other health care providers that share financial and medical responsibility for care provided to a population of patients. New York law requires the Department of Health (DOH) commissioner to promote and regulate the use of ACOs to improve health care services. This law allows the commissioner to issue certificates of authority to ACOs who meet certain requirements, but does not require ACOs to obtain such certification.

The law requires the commissioner to issue regulations delineating safe harbors that exempt ACOs from specified state laws concerning (1) restraint of trade, (2) fee-splitting arrangements, and (3) health care practitioner referrals.

The law also requires the commissioner to engage in state supervision to promote state action immunity under antitrust laws. The state action immunity doctrine (which originated with a 1943 U.S. Supreme Court decision) permits an exception to federal antitrust laws for a private actor's anticompetitive activity if (1) the activity occurs pursuant to a "clearly articulated and affirmatively expressed state policy to displace competition" and (2) the state actively supervises that policy (see, e.g., *F.T.C. v. Phoebe Putney Health System, Inc.*, 133 S.Ct. 1003 (2013)).

New York's ACO law was originally enacted in 2011 as a demonstration program authorizing the commissioner to issue certificates of authority to a maximum of seven ACOs. 2012 legislation extended the program and removed the cap on the number of certificates the commissioner may issue.

On October 15, 2014, the New York DOH published proposed regulations that would establish standards for the commissioner's issuance of certificates of authority to ACOs. The public comment period for the proposed regulations expires on December 1, 2014. Among various other things, the regulations specify the factors that DOH must consider in evaluating requests by ACOs seeking state action immunity from antitrust laws.

Below, we briefly summarize the law and proposed regulations, focusing on the antitrust and other "safe harbor" provisions. Please note that not all provisions of the law or regulations are discussed. DOH's [notice](#) of the proposal includes not only the full text of the proposed regulations but also a brief section-by-section summary and a regulatory impact statement describing various features of the regulations.

NEW YORK LAW ON ACO CERTIFICATION

Overview

New York law requires the DOH commissioner to establish a program "to promote and regulate the use of ACOs to deliver an array of health care services for the purpose of improving the quality, coordination and accountability of services provided to patients" in the state. This law describes an ACO as an organization that:

1. is comprised of clinically integrated health care providers that work together to provide, manage, and coordinate health care (including primary care) for a defined population;
2. has a mechanism for shared governance;
3. has the ability to negotiate, receive, and distribute payments;
4. has accountability for the quality, cost, and delivery of health care to its patients; and
5. has been issued a certificate of authority by the commissioner (N.Y. Pub. Health Law § 2999-p).

The law allows the DOH commissioner, until December 31, 2016, to issue certificates of authority to applicants that meet the conditions for ACO certification he establishes in regulations.

The law requires the commissioner to issue a certificate of authority as a Medicare-only ACO to an entity authorized by the federal Center for Medicaid and Medicare Services (CMS) as an ACO under Medicare, upon receiving an application documenting this status. Such a certificate only applies to the ACO's actions in relation to Medicare beneficiaries. Such Medicare-only ACOs are exempt from certain requirements that apply to other ACOs (N.Y. Pub. Health Law § 2999-p(4)).

Antitrust and Other Laws

The ACO law provides that:

It is the policy of the state to permit and encourage cooperative, collaborative and integrative arrangements among third-party health care payers and health care providers who might otherwise be competitors under the active supervision of the commissioner. To the extent that it is necessary to accomplish the purposes of this article, competition may be supplanted and the state may provide state action immunity under state and federal antitrust laws to payors and health care providers.

The law requires the commissioner to engage in state supervision to promote state action immunity under state and federal antitrust laws. It allows him to require additional documentation and take other actions under the law to verify and make sure that this law is implemented in accordance with its intent and purpose.

The law also requires the commissioner, by regulation, to delineate safe harbors that exempt ACOs from specified state laws concerning (1) restraint of trade, (2) fee-splitting arrangements, and (3) health care practitioner referrals (N.Y. Pub. Health Law § 2999-r).

Other Required Regulations and Requirements

In addition to the safe harbor regulations described above, the commissioner must enact regulations establishing (1) criteria for certificates of authority, (2) quality standards for ACOs, (3) reporting requirements, and (4) other matters deemed appropriate and necessary to operate and evaluate ACOs. The law lists several topics which the regulations may or must address as necessary. The regulations must be consistent, to the extent practical, with CMS' regulations for ACOs under Medicare.

The law addresses a variety of other matters, such as (1) the composition of an ACO's governing body and (2) a prohibition on ACOs limiting or restricting beneficiaries to the use of providers contracted or affiliated with the ACO (N.Y. Pub. Health Law § 2999-q).

PROPOSED REGULATIONS

Among other things, DOH's proposed ACO [regulations](#):

1. specify the applicability of the certification requirement, including the expedited application process for Medicare-only ACOs that meet certain conditions;
2. establish the criteria that must be met for the commissioner to approve a certificate of authority;
3. specify documents and information that must be included with an application for a certificate;
4. require ACOs to ensure provider compliance with quality performance standards and provide certain notifications to patients;
5. set requirements for ACOs concerning the organization's legal structure, governing body, and leadership and management structure;
6. require ACOs to implement a quality management and improvement program;
7. require DOH to collect health care data from ACOs, and make the information available on the department's website (with patient-identifying information removed);
8. set requirements for ACOs that enter payment arrangements with third party payers;
9. specify the grounds and conditions upon which the commissioner may limit, suspend, or terminate an ACO's certificate of authority (including violations of antitrust laws);
10. require ACOs to submit data on various matters to the commissioner; and
11. make various conforming changes concerning independent practice associations.

The proposed regulations do not require ACOs to become certified, and any requirements for ACOs in the regulations only apply to those who are certified or seeking certification as applicable.

Below, this report provides more details on the proposed regulations' provisions on the (1) criteria to grant a certificate of authority and (2) legal protections for ACOs who become certified, including antitrust immunity under the state action doctrine.

Criteria to Grant Certificate

Under the proposed regulations, the commissioner may issue a certificate to an applicant who meets the requirement set forth in the law and regulations (not all requirements apply to Medicare-only ACOs). The proposed regulations require the following conditions to be satisfied for the commissioner to approve an application:

1. the ACO's demonstrated capability to provide, manage, and coordinate health care for a defined population including, where practicable, elevating the services of primary care providers to meet patient centered medical home standards, coordinating services for complex high need patients, and providing access to providers that are not part of the ACO;
2. participation of clinically integrated providers and other ACO participants that are accountable for the quality, cost, and delivery of health care to the ACO's defined population;
3. a governance, leadership, and management structure that is reasonably and equitably representative of the ACO participants and its patients; and
4. documentation of satisfactory character and competence required to conduct the affairs of the ACO in its best interests and in the public interest and so as to provide proper services for patients (Proposed N.Y. Comp. Codes R. & Regs. tit. 10 § 1003.3).

Legal Protections

Antitrust Safety Zone. The proposed regulations provide that a certified ACO is not considered to be in violation of state laws on restraint of trade if the ACO's actions qualify for the "safety zone," subject to the antitrust analysis set forth in the Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, issued by the Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) ([76 Fed. Reg. 67,026](#), October 28, 2011). (The proposed regulations specify that for ACOs that do not participate in one of these CMS programs, certification under the regulations is considered equivalent to participation with CMS.)

The FTC/DOJ policy statement "sets forth a safety zone for certain ACOs that are highly unlikely to raise significant competitive concerns and, therefore, will not be challenged by the Agencies under the antitrust laws, absent extraordinary circumstances." The FTC's [press release](#) announcing the policy states the following about safety zones:

With some exceptions, safety zone eligibility is based on the combined Primary Service Area (PSA) shares of ACO participants that provide a common service . . . to patients from the same PSA. To fall within the safety zone, an ACO's independent participants that provide a common service must have a combined share of 30 percent or less of each common service in each participant's PSA, where two or more participants provide that service to patients in that PSA.

Additional information about the policy statement is available on the FTC's [website](#).

State Action Immunity. Under the proposed regulations, ACOs applying for certification may request that New York provide state action immunity from federal and state antitrust laws. When evaluating these requests, DOH must consider the potential benefits of the ACO's collaborative activities, including the likelihood that any of the following may result:

1. preservation of needed health care services in the relevant primary service area that would be at risk of elimination in the absence of the ACO's collaborative activities;
2. improvement in the nature or distribution of health care services in the primary service area, including expanding needed services or eliminating unnecessary services;
3. enhancing the quality of health care provided by the ACO and its participants;
4. greater access to care for medically-underserved populations;
5. lower health care costs and improved service efficiency, including reductions in administrative and capital costs and improvements in the use of provider resources and equipment; or
6. implementation of payment methodologies that control excess utilization and costs, while improving outcomes (Proposed N.Y. Comp. Codes R. & Regs. tit. 10 § 1003.14).

The department must also consider the following factors when evaluating state action immunity requests:

1. the health care provider landscape of the relevant primary service area, including the (a) availability of suitable and accessible health care services and the level of competition in the area, (b) likelihood that other providers will enter or exit the area, (c) health care workforce, and (d) unique challenges such as difficulties in recruiting and retaining health care professionals;

2. the potential disadvantages of the ACO's collaborative activities;
3. the availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to any reduction in competition;
4. other benefits or disadvantages identified in the review; and
5. the extent to which active supervision is likely to mitigate any disadvantages.

If DOH grants the request, the state must provide active supervision and the ACO must provide materials or information as requested by the department for this purpose. DOH can impose conditions as necessary to ensure that the ACO's activities are consistent with the purposes of the law or necessary to ameliorate potential disadvantages.

Other Safe Harbor Provisions. The proposed regulations provide that, subject to certain conditions:

1. certified ACOs are not considered to be in violation of specified fee splitting laws when certain criteria are satisfied;
2. health care providers who participate in or contract with certified ACOs, and who make referrals to other providers within the scope of the ACO's functions, activities, and services, are not considered to be in violation of specified referral restrictions; and
3. Medicaid providers that enter into arrangements with certified ACOs or ACO participants are not in violation of specified referral restrictions that apply to such providers.

The proposed regulations also provide that the provision of health care services directly or indirectly by an ACO is not considered to be the practice of a profession under the professional licensure laws (Proposed N.Y. Comp. Codes R. & Regs. tit. 10 § 1003.14).

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